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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/564,932
	Filing Date	January 13, 2006
	First Named Inventor	Frank THEOBALD
	Art Unit	1614
	Examiner Name	Unknown
Total Number of Pages in This Submission	Attorney Docket Number	03/058 LTSBOE

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks English translation of the International Preliminary Report on Patentability		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	ProPat, LLC		
Signature	<i>Cathy Moore</i>		
Printed name	Cathy R. Moore		
Date	July 17, 2006	Reg. No.	45,764

CERTIFICATE OF TRANSMISSION/MAILING		
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:		
Signature	<i>Claire Wygand</i>	
Typed or printed name	Claire Wygand	Date July 17, 2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

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28. Juni 2006

ZK PT ~~SW~~ AZ

Date of mailing (day/month/year) 22 June 2006 (22.06.2006)	IMPORTANT NOTIFICATION International filing date (day/month/year) 14 July 2004 (14.07.2004)
Applicant's or agent's file reference 03/058 LTSBOE	
International application No. PCT/EP2004/007770	
Applicant LTS LOHMANN THERAPIE-SYSTEME AG et al	

1. Transmittal of the translation to the applicant.

☐

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

☒

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

KR

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.+41 22 740 14 35	Authorized officer Yolaine Cussac Facsimile No.+41 22 338 70 80
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Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03/058 LTSBOE	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/EP2004/007770	International filing date (day/month/year) 14.07.2004	Priority date (day/month/year) 23.07.2003
International Patent Classification (IPC) or national classification and IPC A61K31/428, A61K9/70		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☒ (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:

☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/007770

Box No. I	Basis of the report
1.	<p>With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.</p> <p><input type="checkbox"/> This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:</p> <p><input type="checkbox"/> international search (Rule 12.3 and 23.1(b))</p> <p><input type="checkbox"/> publication of the international application (Rule 12.4)</p> <p><input type="checkbox"/> international preliminary examination (Rule 55.2 and/or 55.3)</p> <p>2. With regard to the elements of the international application, this report is based on <i>(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)</i>:</p> <p><input type="checkbox"/> the international application as originally filed/furnished</p> <p><input checked="" type="checkbox"/> the description:</p> <p>pages <u>1-10</u> _____ as originally filed/furnished</p> <p>pages* _____ received by this Authority on _____</p> <p>pages* _____ received by this Authority on _____</p> <p><input checked="" type="checkbox"/> the claims:</p> <p>nos. _____ as originally filed/furnished</p> <p>nos.* _____ as amended (together with any statement) under Article 19</p> <p>nos.* <u>1-30</u> _____ received by this Authority on <u>23.05.2005 with letter</u></p> <p>nos.* _____ received by this Authority on <u>of 23.05.2005</u></p> <p><input type="checkbox"/> the drawings:</p> <p>sheets _____ as originally filed/furnished</p> <p>sheets* _____ received by this Authority on _____</p> <p>sheets* _____ received by this Authority on _____</p> <p><input type="checkbox"/> a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.</p> <p>3. <input type="checkbox"/> The amendments have resulted in the cancellation of:</p> <p><input type="checkbox"/> the description, pages _____</p> <p><input type="checkbox"/> the claims, nos. _____</p> <p><input type="checkbox"/> the drawings, sheets/figs _____</p> <p><input type="checkbox"/> the sequence listing (<i>specify</i>): _____</p> <p><input type="checkbox"/> any table(s) related to sequence listing (<i>specify</i>): _____</p> <p>4. <input type="checkbox"/> This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).</p> <p><input type="checkbox"/> the description, pages _____</p> <p><input type="checkbox"/> the claims, nos. _____</p> <p><input type="checkbox"/> the drawings, sheets/figs _____</p> <p><input type="checkbox"/> the sequence listing (<i>specify</i>): _____</p> <p><input type="checkbox"/> any table(s) related to sequence listing (<i>specify</i>): _____</p>

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/007770

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 19-22, 27-30

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 19-22, 27-30

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/007770

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	<u>16, 21</u>	YES
	Claims	<u>1-15, 17-20, 22-30</u>	NO
Inventive step (IS)	Claims	<u></u>	YES
	Claims	<u>1-30</u>	NO
Industrial applicability (IA)	Claims	<u>1-18, 23-26</u>	YES
	Claims	<u></u>	NO
2. Citations and explanations (Rule 70.7)			
See Supplemental Box.			

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Continuation of Boxes III and V

BOX III

**Non-establishment of opinion with regard to novelty,
inventive step and industrial applicability**

Claims 19 to 22 and 27 to 30 relate to subject matter which, in the opinion of this Authority, falls under **PCT Rule 67.1(iv)**. Consequently no expert opinion has been established regarding the industrial applicability of the subject matter of these claims (**PCT Article 34(4)(a)(i)**).

BOX V

**Reasoned statement with regard to novelty, inventive step
and industrial applicability; citations and explanations
supporting such statement**

This report refers to the following documents:

- D1:** EP 0 428 038 A (BOEHRINGER INGELHEIM), 22 Mai 1991
(1991-05-22)
- D2:** WO 03/015779 A (HEXAL), 27 February 2003 (2003-02-27)
- D3:** WO 02/03969 A (HEXAL), 17 January 2002 (2002-01-17)
- D4:** WO 00/74661 A (NOVEN PHARMACEUTICALS), 14 December 2000
(2000-12-14)
- D5:** WO 03/011291 A (HEXAL), 13 February 2003 (2003-02-13)
- D6:** WO 96/18395 A (UPJOHN), 20 June 1996 (1996-06-20)

Supplemental Box

1. The PCT Contracting States do not have uniform criteria against which the industrial applicability of **claims 19 to 22 and 27 to 30** in the present application can be assessed. Patentability may depend on the wording of the claims. For example, the European Patent Office does not recognise the industrial applicability of claims to the medical use of a compound. It may, however, allow claims to the first medical use of a known compound or to the use of such a compound in the preparation of a drug for a new medical application.
2. The application fails to meet the requirements of **PCT Article 33(1)** because the subject matter of **claims 1, 3, 4, 7 to 15, 19, 20, 22 to 24, 26 to 28 and 30** is not novel (**PCT Article 33(2)**) over document D1.

Document D1 describes a transdermal therapeutic system for treating **schizophrenia** and **parkinsonism**, consisting of a back layer, a peel-off protective film and **an active-principle-containing film reservoir**, exactly as in the present invention, **the active principle (Pramipexol or its (-) enantiomer) being contained in an emulsion polymerised polyacrylate polymer layer**. The polyacrylate polymer layer is of the type Eudragit NE 30 D (R) **(a mixture of carboxyl-group-free polymerised acrylic esters and methacrylic esters)**. The system can apply between 0.5 and 5 mg of the active principle per day with a flow rate of more than 10 micrograms/cm² h (see D1, page 2, lines 40 to 50; also the claims, example 1 and figure I).

The subject matter of **claims 1 to 9, 14, 19, 22, 23,**

Supplemental Box

25 to 27, 29 and 30 lacks novelty (**PCT Article 33(1) and 33(2)**) over document **D2**.

Document D2 discloses (the references in parentheses are to **D2**) a transdermal therapeutic system for treating **parkinsonism**, consisting of a cover layer, a peel-off protective film and one (or more) **active-principle-containing matrix layer(s)**, the **active principle (Pramipexol or salts or solvates thereof)** being contained in an **polyacrylate polymer layer**. The polyacrylate polymer layer can be of the type **Durotak 2287 (R)**, exactly as in the present invention (see **D2**, page 4, third paragraph to page 8, first paragraph; also the claims and examples).

In a similar way the subject matter of **claims 1 to 9, 14, 17 to 19, 23 and 27** lacks novelty (**PCT Article 33(1) and 33(2)**) over document **D3**.

Document D3 discloses (the references in parentheses are to **D3**) a transdermal therapeutic system comprising a cover layer, a peel-off protective film and **one (or more) active-principle-containing self-adhesive matrix layer(s)**, in which the **active principle, which can be an antiparkinsonism agent such as Pramipexol**, is contained in an **polyacrylate polymer layer**. The polyacrylate polymer layer can be of the type **Durotak (R)**, exactly as in the present invention (see **D3**, page 13, third paragraph; page 8, first paragraph to page 9, first paragraph; and the claims). **The system can contain penetration promoters (such as silicon dioxide or alcohols such as 1,2-propane diol) or stabilisers.**

Supplemental Box

In a similar way the subject matter of **claims 1 to 9, 14, 17 to 19, 23 and 27** lacks novelty (PCT Article 33(1) and 33(2)) over document **D4**.

Document D4 discloses (the references in parentheses are to **D4**) a transdermal therapeutic system comprising **an active-principle-containing self-adhesive matrix layer**, in which the active principle, which can be an antiparkinsonism agent such as **Pramipexol**, is contained in an **polyacrylate polymer layer**. The polyacrylate polymer layer, which can be of the type **Durotak (R)**, exactly as in the present invention, contains a polymerised hydroxyl-group-containing acrylic ester (see *D4*, page 18, first paragraph; and the claims and examples). **The system can contain penetration promoters (such as alcohols or diols such as 1,2-propane diol) or stabilisers (such as esterified cellulose derivatives)**. The subject matter of **claims 1 to 15, 17 to 20 and 22 to 30** therefore lacks novelty (PCT Article 33(1) and 33(2)).

3. **The application fails to meet the requirements of PCT Article 33(1) because the subject matter of claims 1 to 30 does not involve an inventive step (PCT Article 33(3)).**

Regarding the subject matter of **claims 1 to 30**, documents **D1 to D4** appear to be of particular relevance in connection with the question of inventive step. They in fact solve **the same problem**, namely that of providing transdermal therapeutic systems comprising a back layer

Supplemental Box

and an active-principle-containing polymer matrix, and containing **an antiparkinsonism agent such as Pramipexol (or its (-) enantiomer or salts or solvates thereof)**. The active-principle-containing polymer matrix is a **polyacrylate polymer layer** created from a **mixture of carboxyl-group-free and hydroxyl-group-containing polymerised acrylic esters and methacrylic esters**. These transdermal therapeutic systems are designed to have a particular daily release rate and flow rate.

Regarding the subject matter of **claims 16 and 21**, it seems to be normal to choose a specific concentration of the active principle and to use Pramipexol as a neuroprotective drug (the neuroprotective action of Pramipexol is well established; see document D6).

The present application therefore does not appear to meet the requirements of **PCT Article 33(1) and 33(3)** with respect to the aforementioned documents in so far as novelty is concerned.